IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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6-29-02

In re application of:	Confirmation No.
Konopitzky, *et al.*	Art Unit: 1642
Appl. No. 09/631,863	Examiner: Minh-Tam Davis
Filed: August 3, 2000	Atty. Docket: 0652.2480001/EKS/CML
For: **Tumor-Associated Antigen (R11)**	

Reply To Restriction Requirement

Commissioner for Patents
Washington, D.C. 20231

Sir:

In reply to the Office Action dated May 22, 2002, requesting an election of one invention to prosecute in the above-referenced patent application, Applicants hereby provisionally elect to prosecute the invention of Group I, represented by claims 1-5, 17, 33-34, drawn to a tumor associated antigen of SEQ ID NO:2, and fragments thereof of SEQ ID NOs:88-102. Further, Applicants elect the full length species of Group I. This election is made without prejudice to or disclaimer of the other claims or inventions disclosed.

This election is made with traverse.

Applicants respectfully traverse the restriction requirement as it applies to Groups I-XXXXI. It is the Examiner's position that each of such groups are distinct inventions because:

> (1) the process for using the product as claimed can be practiced with another materially different product or
>
> (2) the product as claimed can be used in a materially different process of using that product

See Paper 10, page 8.

However, even where two patentably distinct inventions appear in a single application, restriction remains improper unless the Examiner can show that the search and examination of both groups would entail a "serious burden" (*see* MPEP § 803).

In the present situation, the Examiner has not shown that examination of the above-identified groups imposes a "serious burden." The products and processes of use as claimed are related. Indeed, the claims are all directed to tumor associated antigen designated R11-ORF-1, as a nucleic acid encoding protein, protein, protein fragment, method of treatment, or pharmaceutical composition for treating or preventing cancer.

Moreover, Groups II, III, VIII, IX, X, XV, XVI, XVII, XVIII, XXVIII, XXIX, XXXX, and XXXXI are classified in Class 530, and Groups IV, V, XI, XII, XXII-XXVII, are classified in Class 514, Groups VI, VII, XIII, XIV, and XXX-XXXIII are classified in Class 424, Groups XIX-XXI, are classified in class 536 and finally Groups XXXIV-XXXIX are classified in class 435. The classifications are therefore limited and have considerable overlap between the groups. Applicants submit that a search of Group II would provide useful information for Groups III, VIII, IX, X, XV, XVI, XVII, XVIII, XXVIII, XXIX, XXXX, and XXXXI. In addition, the claimed protein fragments and derivatives, and nucleic acids encoding such proteins fragments and derivatives, have functional activities of the R11-ORF-1 tumor associated antigen. Therefore, a search of any such subset, or a search of a particular functionality i.e., inducing or augmenting an immune response, or treating or preventing cancer, employing R11-ORF-1 tumor associated antigen will necessarily provide useful information for each subset. Therefore the searches are co-extensive and would not impose a "serious burden" for examination together.

The claims of Group I are related to the claims of Groups IV, V, VI, and VII between a product (Group I) and a method for using the product (Groups IV, V, VI, and VII), and further, the method claims comprising Groups IV, V, VI, and VII depend from and include all the limitations of the product claims of Group I. In light of the decisions in *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995) and *In re Brouwer*, 77 F.3d 422, 37 USPQ 2d 1663 (Fed. Cir. 1996), a notice was published in the Official Gazette which set forth new guidelines for the treatment of product and process claims. *See* 1184 OG 86 (March 26, 1996). Specifically, the notice states that:

> in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim depends from or otherwise includes all the limitations of an allowed product claim.

Id. Accordingly, if claims of Group I are found allowable, Applicants respectfully request that the claims of Groups IV, V, VI, and VII be rejoined and examined for patentability. *See also* M.P.E.P. § 821.04.

Examiner also required election of a full length sequence *or* fragments thereof. *See* Paper 10, page 9. Applicants assert that a search of the full length sequence or fragment thereof is coextensive and would not place a "serious burden" on the Examiner. Pursuant to M.P.E.P. § 809.02(a), when such an election is required the Examiner should identify generic claims or indicate that no generic claims are present and clearly identify each of the disclosed species to which claims are restricted. Examiner has not taken any such action.

Further, Applicants point out that the Examiner has not addressed MPEP § 803.04, directed to nucleotide sequences. Pursuant to the notice *Examination of Patent Applications Containing Nucleotide Sequences*, 1192 O.G. 68 (November 19, 1996), §803.04 holds that even when nucleotide sequences encoding different proteins are contained in an application, a reasonable number, normally ten sequences, will be examined in a single application. Thus, Applicants respectfully submit that the present requirement for election is improper. However, even if the Examiner contends that the instant nucleic acids encode different proteins within the scope of §803.04, Applicants submit that a reasonable number of such nucleic acids should be examined together, and the Examiner has given no indication why ten sequences are unreasonable in the present case. Additionally, Applicants note that if an elected species is found allowable, it is proper for the Examiner to examine the next sequence within the same application.

Reconsideration and withdrawal of the Restriction Requirement, and consideration and allowance of all pending claims, are respectfully requested. It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents.

However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefore are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

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June 24, 2002

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Commissioner for Patents
Washington, D.C. 20231

Art Unit 1642

Re: U.S. Utility Patent Application
Appl. No. 09/631,863; Filed: August 3, 2000
For: **Tumor-Associated Antigen (R11)**
Inventors: Konopitzky *et al.*
Our Ref: 0652.2480001/EKS/CML

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Reply to Restriction Requirement; and
2. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

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EKS/CML:dms
Enclosures
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